

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

DEY, L. P. and DEY, INC.,

Plaintiffs,

V.

Civil Action No. 1:09-cv-87

**TEVA PARENTERAL MEDICINES, INC.,
TEVA PHARMACEUTICALS USA, INC.,
and TEVA PHARMACEUTICAL
INDUSTRIES, LTD.,**

Judge Irene M. Keeley

Defendants.

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT TEVA'S
MOTION *IN LIMINE* TO PRECLUDE ANY EVIDENCE OF
OR REFERENCE TO ALLEGED COPYING**

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I. INTRODUCTION

Defendants Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. (collectively “Teva”) submit this memorandum in support of Teva’s motion *in limine* to preclude Plaintiffs Dey, L.P. and Dey, Inc. (collectively “Dey”) from introducing or relying on evidence of alleged copying as an objective consideration of nonobviousness of the patents-in-suit.

This case stems from Teva’s filing of an Abbreviated New Drug Application (ANDA) under the Hatch-Waxman Act, seeking approval to market a generic formoterol fumarate inhalation solution drug product. Following FDA requirements, Teva developed its formoterol fumarate inhalation solution as a generic to the reference listed drug, Perforomist[®]. Teva’s compliance with the regulatory requirements for establishing bioequivalence of its ANDA product with the reference listed drug is irrelevant to the question of obviousness of the patents-in-suit.¹ Teva respectfully requests that the Court preclude Dey from relying on evidence of alleged copying to support its position that the patents-in-suit are not invalid as obvious under 35 U.S.C. § 103.

II. EVIDENCE OF COPYING IN THE CONTEXT OF AN ANDA IS IRRELEVANT TO THE QUESTION OF OBVIOUSNESS AND SHOULD BE EXCLUDED

Dey should be precluded from introducing or relying on evidence of alleged copying by Teva as an objective consideration of the obviousness of the patents-in-suit. Evidence of copying in an ANDA case, as here, is not relevant to the issue of obviousness because FDA law obligates the ANDA filer to copy the brand’s active pharmaceutical ingredient and label, and to

¹ Any alleged evidence of copying by Teva also lacks the required nexus with the claimed invention. *See Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). This issue is addressed in Defendant Teva’s Motion *in Limine* to Preclude Evidence of Alleged Objective Considerations of Nonobviousness Lacking a Nexus with the Claimed Inventions.

have a product that is bioequivalent to the branded product. *See Bayer Healthcare Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013); *see also Hospira Inc. v. Sandoz Inc.*, 2012 WL 1587688, *27 (D.N.J. May 4, 2012) (holding that evidence of copying was not persuasive as an objective consideration of nonobviousness in the context of generic pharmaceutical litigation because the law obligates a generic drug company to copy the brand's active ingredient and label); *Santarus, Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427, 458-59 (D. Del. 2010) (“[A] showing of copying is not compelling evidence of non-obviousness in Hatch-Waxman cases due to the nature of the ANDA process.”), *rev'd on other grounds*, 694 F.3d 1344 (Fed. Cir. 2012). The Federal Circuit stated, “[E]vidence of copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval.” *Bayer*, 713 F.3d at 1377 (citing *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 377 Fed. Appx. 978, 983 (Fed. Cir. 2010)).

Thus, any alleged evidence of copying by Teva is not admissible because it is not relevant, as it does not have any tendency to make a fact that is of consequence in determining the action more or less probable than it would be without the evidence. Fed. R. Evid. 401.

III. CONCLUSION

Evidence of Teva's alleged copying of the reference listed drug Perforomist[®] is not relevant to whether the patents-in-suit are obvious. Teva respectfully requests that the Court grant its motion to preclude Dey from introducing or relying on evidence of alleged copying to support its contention that the patents-in-suit are not invalid or obvious.

Dated this 14th day of June 2013.

**DEFENDANTS, TEVA PARENTERAL MEDICINES,
INC., TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES, LTD., By
Counsel:**

By: /s/ Bruce M. Gagala

Bruce M. Gagala (IL State Bar #0901342)

Jeffrey B. Burgan (IL State Bar #6203895)

Leydig, Voit & Mayer, Ltd.

Two Prudential Plaza - Suite 4900

180 North Stetson Avenue

Chicago, IL 60601-6780

Telephone: (312) 616-5600

Facsimile: (312) 616-5700

E-Mail: BGagala@Leydig.com

JBurgan@Leydig.com

/s/ Geraldine S. Roberts

James A. Varner, Sr. (WV State Bar #3853)

Geraldine S. Roberts (WV State Bar #3126)

McNeer, Highland, McMunn and Varner, L.C.

Empire Building - 400 West Main Street

P. O. Drawer 2040

Clarksburg, WV 26302-2040

Telephone: (304) 626-1100

Facsimile: (304) 623-3035

E-Mail: JAVarner@wvlawyers.com

GSRoberts@wvlawyers.com

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and TEVA PHARMACEUTICAL)	
INDUSTRIES, LTD.,)	
)	
Defendants.)	

CERTIFICATE OF SERVICE

This certifies that on this 14th day of June 2013, counsel for the defendants served the following document: **“MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT TEVA’S MOTION *IN LIMINE* TO PRECLUDE ANY EVIDENCE OF OR REFERENCE TO ALLEGED COPYING”** upon counsel of record via: (1) electronic notification through the Court’s CM/ECF system; and/or (2) via facsimile, and/or (3) via hand delivery, and/or (4) via electronic mail transmission as previously agreed upon by the parties:

Gordon H. Copland, Esquire
William J. O’Brien, Esquire
Step toe & Johnson PLLC
400 White Oaks Blvd.
Bridgeport, WV 26330
Fax (304) 933-8183

David R. Marriott, Esquire
David N. Greenwald, Esquire
Evan R. Chesler, Esquire
Roger G. Brooks, Esquire
Cravath, Swaine & Moore LLP
825 Eighth Avenue
New York, NY 10019
Fax (212) 474-3700

Co-Counsel for Plaintiffs

/s/ Geraldine S. Roberts
Geraldine S. Roberts (WV State Bar #3126)